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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,503	03/10/2000	Michael A. Masini	MED-02702/29	4920

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EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/523,503	Applicant(s) MASINI, MICHAEL A.	
	Examiner Eduardo C. Robert	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment wherein the apparatus further includes a prosthesis installable on the distal femur, as per claim 15, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Figures 1-4 appear to be prior art, as disclosed in the specification, thus figures 1-4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

The drawings are objected to because Figures 1, 4, 3B, 5, 7, 8A-8C, PA, and 9B contain extraneous matter, e.g. distal cutting guide, etc., which is not permitted and should be removed. Correction is required.

Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

- a) A separate letter to the Draftsman in accordance with MPEP § 608.02(r); and
- b) A print or pen-and-ink sketch showing changes in red ink in accordance with MPEP § 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink is required in response to this Office Action, and may not be deferred.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 12-15 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, lines 3-4, applicant positively recites part of a human, i.e. "a movable member which references one of a non-prominent and trochlear regions". Thus claims 12-15 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Specification

The specification is objected to as failing to provide clear support for the claim terminology. 37 CFR § 1.75(d)(1) requires that terms and phrases used in the claims find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. Specifically, the terms "movable member", "movable guide", "reference guide" do not appear in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 14, lines 1 and 2, applicant recites the fixture further including “a medial-to-lateral slide” in addition to the “movable member” of claim 12, thus it is unclear and indefinite what applicant considers to be the “movable member”, e.g. an assembly comprising rod 112, surface 114, member 116, and cutting block 120; or the slidable member 112; or the cutting block, 120. Furthermore, in line 2, “the reference guide” lacks a prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13, 15, and 16, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Whiteside.

Whiteside discloses an apparatus comprising a fixture (see Figure 8) including a movable member 81, and a cutting guide 80. The apparatus further comprises an intramedullary rod 30 and a reference guide 82. The movable member 81 and reference guide 82 are movable along the rod 30. The apparatus also comprises a prosthesis (see Figure 23). Whiteside further discloses a method including the steps of installing the fixture onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figure 20) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of

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the fixture, until the guide touches the non-prominent condyle or trochlear region (see Figure 20).

Claims 8-13 and 16, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by White.

White discloses an apparatus comprising a fixture (see Figure 1) including a movable member, and a cutting guide 113. The apparatus further comprises an intramedullary rod 37 and a reference guide 91. White further discloses a method including the steps of installing the fixture onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figures 9-19) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of the fixture, until the guide touches the non-prominent condyle or trochlear region.

Applicant is reminded that an anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, **either expressly or under principles of inherency**, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data System, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). Furthermore, it is well settled that **the law of anticipation does not required that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference**, i.e. all limitation of the claims are found in the reference. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, **it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently**

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discloses that element or limitation. *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

Response to Arguments

Applicant's arguments filed on January 14, 2002 have been fully considered but they are not persuasive.

In response to applicant's argument that Whiteside is entirely silent with regard to referencing any feature of the distal femur, it is noted that Whiteside clearly refers to or indicates the non-prominent condyle or trochlear region (see Figure 20). Furthermore, **it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation.** *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

In response to applicant's argument that Whiteside does not have a movable member which references one of non-prominent condyles or trochlear regions, it is noted that this recitation in claim 12 is considered non-statutory subject matter since applicant positively recites part of a human which is non-statutory. A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

In response to applicant's argument that claim 12 includes a limitation that the cutting guide is used to resect a femur in accordance with the reference made, it is noted that the manner

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in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to Applicant's argument that White does not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., measuring the distal end of either condyle or the trochlear region) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

Allowable Subject Matter

Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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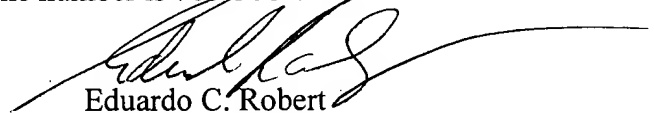
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333.

The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C. Robert
April 4, 2002